510K SUMMARY

MAY - 1 2012

510K:	k111928
Submitted By:	Psychemedics Corporation 5832 Uplander Way Culver City, CA 90230 TEL: 310 216 7776 FAX: 310 216 6662
Submission Contact:	Virginia Hill
Date Prepared:	April 25, 2012
Device Trade Name:	Psychemedics Microplate EIA for Phencyclidine in Hair
Predicate Device:	Psychemedics Phencyclidine Assay, k011275
Product Code:	LCM
Device Classification/Name:	Enzyme Immunoassay, Phencyclidine, Unclassified
Intended Use:	The Psychemedics Microplate EIA for Phencyclidine is an enzyme immunoassay (EIA) for the preliminary qualitative detection of phencyclidine in human head and body hair samples using a phencyclidine calibrator at 3 ng /10 mg hair cutoff for the purpose of identifying phencyclidine use. This is an *in vitro* diagnostic device intended exclusively for Psychemedics use only and is not intended for sale to anyone. The Psychemedics EIA Phencyclidine Assay provides only a preliminary analytical test result. To obtain a quantitative analytical result or to confirm positive results, a more specific alternate chemical method (e.g. GC/MS) must be used. Clinical consideration and professional judgment should be applied to the interpretation of any drug-of-abuse test result.
Assay Description:	The test consists of two parts; a **pre-analytical** hair treatment procedure (to convert the solid matrix of hair to a measurable liquid matrix) and the **screening assay**, the Psychemedics Microplate EIA for Phencyclidine. The drug is recovered from the hair using a patented method (U.S. Patent #8,084,215).The screening portion of the test system consists of (1) microplate wells coated with multiple drugs including phencyclidine conjugated to bovine serum albumin (BSA) (patent pending), polyclonal rabbit anti-phencyclidine, goat anti-rabbit secondary antibody conjugated to HRP (horseradish peroxidase), substrate [3, 3', 5, 5' tetramethylbenzidine (TMB)], HCl to acidify the final reaction, and wash buffer for washing the plates. Absorbance in the wells is read with a microplate reader.
Sample Collection:	A sample of hair should be cut as close as possible to the skin. The hair is placed in a V-shaped aluminum foil sample holder with the root end of

the hair protruding beyond the slanted edge of the foil. The aluminum foil is crimped around the sample, securing the hair specimen firmly into place within the foil. The hair samples crimped within the foil is placed in a sample acquisition card envelope and the envelope is sealed with a tamper-evident seal. Hair specimens are kept at ambient temperature in a secure location until they are shipped without refrigeration to the laboratory.

Materials required: Hair sample collection kit, Microplate for PCP EIA, Microplate washer and reader, GC/MS for confirmation.

Comparison of Psychemedics Microplate EIA for PCP with Psychemedics RIA Assay for PCP

Item	Device	Predicate
Indications for Use	The Psychemedics Microplate EIA for Phencyclidine is an enzyme immunoassay (EIA) for the preliminary qualitative detection of phencyclidine in human head and body hair samples using a phencyclidine calibrator at 3 ng /10 mg hair cutoff for the purpose of identifying phencyclidine use. This is an *in vitro* diagnostic device intended exclusively for Psychemedics use only and is not intended for sale to anyone. The test is not intended for over the counter sale to nonprofessionals. The Psychemedics EIA Phencyclidine Assay provides only a preliminary analytical test result. To obtain a quantitative analytical result or to confirm positive results, a more specific alternate chemical method (e.g. GC/MS) must be used. Clinical consideration and professional judgment should be applied to the interpretation of any drug-of-abuse test result.	The Psychemedics PCP assay is a radioimmunoassay (RIA) for the preliminary detection of phencyclidine (PCP) in hair using a 3 ng/10 mg hair cutoff for the purposes of identifying PCP use. For a quantitative analytical results or to confirm positive results *via* the presence of PCP, a more specific alternate chemical method must be used in order to obtain a confirmed analytical results
510k	K111928	K011275
Measurand	Phencyclidine	Phencyclidine
Matrix	Human head or body hair	Human head or body hair
Cutoff concentration	3 ng phencyclidine/10 mg hair	3 ng phencyclidine /10 mg hair
Type of Test	Enzyme Immunoassay	Radioimmunoassay
Method of measurement	Microplate reader	Gamma counter
Extraction Method	Nonproteolytic Digestion	Proteolytic Digestion
Confirmation	GC/MS	GC/MS

Summary of Performance Testing:

Precision Studies

Intra-Assay		
LEVEL	NEG	POS
B_0 (-100%)	15	0
-75%	15	0
-50%	15	0
-25%	15	0
plus 25%	0	15
plus 50%	0	15
plus 75%	0	15
plus 100%	0	15

Inter-Assay		
LEVEL	NEG	POS
B_0 (-100%)	75	0
-75%	75	0
-50%	75	0
-25%	75	0
plus 25%	0	75
plus 50%	0	75
plus 75%	0	75
plus 100%	0	75

Agreement Testing

One-hundred-forty negative samples, twenty-four samples below the cutoff, 15 samples between the cutoff and+100% of the cutoff , and 46 samples ≥100% of the cutoff, were confirmed by GC/MS, and an additional 224 negative samples were compared to the predicate. Of the total samples, 15% were body hair samples.

LC/MS/MS:	≤ -10 % of Cutoff	Between -10% and -50% of Cutoff	Between -50% and Cutoff	Between Cutoff, And +50%	Between +50% and +100%	> +100% of cutoff
EIA Positive	0	0	2	8	7	46
EIA Negative	140	1	13	0	0	0

	Negative by Predicate	Positive by Predicate
EIA Positive	0	53
EIA Negative	364	0

Cosmetic Treatment Study

Twenty PCP-negative hair samples were treated with bleach, 20 with permanent wave, 20 with dye, 20 with relaxer, and 20 with shampoo, and the results compared to the same samples without the treatments. In each case of the 20 samples treated with a type of cosmetic treatment, 10 samples were treated with one brand of a particular product and 10 other samples with a second brand. No significant differences were observed for the negative hair samples before and after the treatments; all samples remained negative after the treatments.

Twelve PCP-positive hair samples were treated with bleach, 12 with permanent wave, 12 with dye, 12 with relaxer, and 12 with shampoo, and the results compared to the same samples without the treatments. In each case of the 12 samples treated with a type of cosmetic treatment, 6 samples were treated with one brand of a particular product and 6 other samples with a second brand. The average of the EIA B/B_0 x 100 values obtained for the samples in each set before treatment is shown, with the range following in

parenthesis. In the second row of the table, the average of the EIA B/B_0 x 100 values obtained for the samples in each set after treatment is shown, with the range following in parenthesis. No samples positive for PCP became negative after cosmetic treatment.

Treatment Status	Bleach	Dye	Perm	Relaxer	Shampoo
	Mean (Range) of B/B_0 x 100 Values of 12 PCP-Positive Samples in PCP EIA				
Before	35.3 (22.0 – 48.4)	35.3 (17.0 – 53.8)	40.0 (23.2 – 63.7)	34.3 (23.2 – 53.8)	33.4 (17.0 – 56.3)
After	34.0 (19.4– 50.8)	35.8 (17.0 – 53.1)	40.2 (22.8 – 63.7)	35.6 (25.0 – 49.5)	34.3 (17.7 – 54.7)

Contamination Study

Contamination of 8 hair samples by soaking in 1000 ng phencyclidine /mL of water resulted in a range of phencyclidine on the hair of 138.5 to 265.4 ng of phencyclidine /10 mg hair before washing. After washing by the procedure described in (2) above, the amount of phencyclidine remaining on the hair samples ranged from 3.3 to 16.4 ng/10 mg hair, with all samples appearing to be positive before application of the wash criterion. After application of the wash criterion (see below), all of these samples containing phencyclidine above the cutoff were determined to be contaminated rather than positive.

Contamination of 8 hair samples by soaking in 1000 ng phencyclidine /mL of saline resulted in a range of phencyclidine on the hair of 38.1 to 88.9 ng of phencyclidine /10 mg hair before washing. After washing by the procedure described below, the amount of phencyclidine remaining on the hair samples ranged from 0.7 to 3.0 ng/10 mg hair, with one sample at the cutoff. Seven of the 8 samples were negative (i.e., below the cutoff) even without application of the wash criterion. After application of the wash criterion, the one sample at the cutoff was determined to be contaminated rather than positive.

The Wash Procedure

a. Wash by Psychemedics' standard wash procedure:
    i. Add 2 mL of dry isopropanol and shake in waterbath for 15 minutes at 37°C with shaking @ 100 -120 oscillations/minute.
    ii. Add 2 mL of Wash Buffer (0.01 M phosphate buffer, pH 6.0, with 0.1% BSA) and shake in waterbath for 30 minutes at 37°C with shaking @ 100 -120 oscillations/minute.
    iii. Repeat Step ii. two more times
    iv. Add 2 mL of Wash Buffer and shake in waterbath for 60minutes at 37°C with shaking @ 100 -120 oscillations/minute.
    v. Repeat Step iv. one more time
    vi. Save wash from Step v.
b. Analyze the last wash for phencyclidine.

Confirmation and Interpretation

c. a. Perform confirmation procedures for PCP.
d. b. Calculate wash criterion:
    i. Multiply the last wash value x 5.
    ii. Subtract the value of the drug in the last wash from the value of the drug in the digested hair.
    iii. If the result is less than the cutoff for the drug in the hair, the sample is interpreted as contaminated. If the result is $\geq$ the parent drug cutoff, the sample is interpreted as positive due to ingestion. The parent-drug cutoff value for PCP is 3ng/ 10 mg hair.

Cross-reactivity and Interference Studies

Two compounds, shown in the table below, showed cross-reactivity in the PCP assay. Sixty-four other compounds showed no cross-reactivity in the assay. One-hundred-twenty-eight compounds tested for interference at +/-50% of the cutoff showed no interference in the assay.

Cross-reactivity of related Compounds in Phencyclidine EIA

Compound	Amount of Compound required to Produce a positive test at the cutoff of 3 ng phencyclidine/10 mg hair	Percent Cross-reactivity*
1-(1-Phenylcyclohexyl) morpholine (PCM)	60	5.0
Metaphit	10	30

Stability of Calibrator and Control Solutions

The PCP calibrator and control solutions are prepared in-house by the laboratory from certified standards. Stability of PCP in methanol in the presence of other drugs of abuse was shown to exceed 1 year.

Recovery Study

Recovery of PCP from hair of PCP users was shown to be substantially equivalent to the method of the predicate device.

Conclusion:

The Psychemedics Microplate EIA for Phencyclidine in Hair is substantially equivalent to the predicate device k011275, and the results are substantially equivalent to GC/MS results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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Silver Spring, MD 20993

Psychemedics Corporation
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5832 Uplander Way
Culver City, CA 93065

MAY - 1 2012

Re: k111928

Trade/Device Name: Psychemedics Microplate EIA for Phencyclidine in Hair
Regulation Number: 21 CFR 862.3100
Regulatory Class: Unclassified
Product Code: LCM
Dated: March 9, 2012
Received: March 12, 2012

Dear Ms. Hill:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number : k111928

Device Name: Psychemedics Microplate EIA for Phencyclidine in Hair

Indications For Use:

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Prescription Use ____ (21 CFR Part 801 Subpart D)	And/Or	Over the Counter Use __X__ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k111928